

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC. and SCIELE  
PHARMA CAYMAN LTD.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS, INC. and  
MYLAN LABORATORIES, INC.,

Defendants.

C.A. No. 07-664-GMS

**JURY TRIAL DEMANDED**

**PLAINTIFFS' REPLY TO DEFENDANTS' COUNTERCLAIMS**

Plaintiffs Sciele Pharma, Inc. and Sciele Pharma Cayman Ltd. (collectively, "Sciele" or "Plaintiffs"), by their attorneys, Fish & Richardson P.C., reply to the Counterclaims of Defendants Mylan Pharmaceuticals, Inc. and Mylan Laboratories, Inc. (collectively, "Mylan" or "Defendants"). Except as expressly admitted below, Plaintiffs deny each and every allegation in Defendants' Counterclaims. Specifically, Plaintiffs reply as follows:

**The Parties**

1. Mylan Pharms is a corporation organized under the laws of the State of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

**REPLY:**

Admitted.

2. Mylan Laboratories, Inc. (now known as Mylan Inc.) is a corporation organized under the laws of the State of Pennsylvania, having an office and place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

**REPLY:**

Admitted.

3. Plaintiff Sciele Pharma, Inc. purports to be a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 5 Concourse Parkway, Suite 1800, Atlanta, Georgia 30328.

**REPLY:**

Plaintiff Sciele Pharma, Inc. admits that it is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 5 Concourse Parkway, Suite 1800, Atlanta, Georgia 30328.

4. Plaintiff Sciele Pharma Cayman Ltd. purports to be a corporation organized and existing under the laws of the Cayman Islands with a principal place of business at Ugland House, South Church Street, Georgetown, Grand Cayman, Cayman Islands.

**REPLY:**

Plaintiff Sciele Pharma Cayman Ltd. admits that it is a corporation organized and existing under the laws of the Cayman Islands with a principal place of business at Ugland House, South Church Street, Georgetown, Grand Cayman, Cayman Islands.

**Jurisdiction and Venue**

5. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

**REPLY:**

Sciele admits that Mylan's counterclaim arises under 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, but denies that Mylan is entitled to any relief under these statutes.

6. In the event and to the extent this Court has subject matter jurisdiction over Sciele's action, this Court also has original jurisdiction over the subject matter of this Counterclaim under 28 U.S.C. §§ 1331 and 1338(a).

**REPLY:**

Sciele admits that the Court has subject matter jurisdiction over both Sciele's action and Mylan's counterclaim under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Plaintiffs because Plaintiffs have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Mylan in this District, and/or because Plaintiffs conduct substantial business in this District.

**REPLY:**

Sciele admits that the Court has personal jurisdiction over it. Sciele denies any remaining allegations of paragraph 7.

8. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

**REPLY:**

Admitted.

**Patent-in-Suit**

9. On or about January 9, 1990, the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,892,741 ("the '741 patent"), entitled "Press Coated DHP Tablets," to Andreas Ohm, Helmut Luchtenberg, Shinji Maegata and Wolfgang Opitz.

**REPLY:**

Admitted.

10. On or about October 22, 2007, Plaintiffs sued Mylan in this District alleging infringement of the '741 patent under 35 U.S.C. § 271(e)(2)(A).

**REPLY:**

Admitted.

**Count I**

**(Declaratory Judgment of Non-Infringement of the '741 Patent)**

11. Mylan re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

**REPLY:**

Sciele re-asserts and re-alleges its replies to each of the foregoing paragraphs as though fully set forth herein.

12. The manufacture, use, sale, offer for sale, or importation of the nisoldipine tablets that are the subject of Mylan Pharms' ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '741 patent.

**REPLY:**

Sciele incorporates its claim of infringement set forth in its Complaint. Sciele also denies that Mylan is entitled to any judgment of invalidity or unenforceability of the '741 patent.

13. Mylan is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the nisoldipine tablets that are the subject of Mylan Pharmaceuticals, Inc.'s ANDA have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '741 patent.

**REPLY:**

Sciele incorporates its claim of infringement set forth in its Complaint. Sciele also denies that Mylan is entitled to any judgment of invalidity or unenforceability of the '741 patent.

**Demand for Jury Trial**

Plaintiffs demand a trial by jury on all issues appropriately tried to a jury.

Dated: January 28, 2008

FISH & RICHARDSON P.C.

By: /s/ William J. Marsden, Jr.

William J. Marsden, Jr. (#2247)  
Susan M. Coletti (#4690)  
919 N. Market Street, Suite 1100  
P.O. Box 1114  
Wilmington, DE 19899-1114  
Telephone: (302) 652-5070  
Facsimile: (302) 652-0607  
Email: marsden@fr.com; coletti@fr.com

Jonathan E. Singer  
Deanna J. Reichel  
3300 Dain Rauscher Plaza  
60 South Sixth Street  
Minneapolis, MN 55402  
Telephone: (612) 335-5070  
Facsimile: (612) 288-9696

Nagendra Setty  
1180 Peachtree Street, N.E., 21st Floor  
Atlanta, GA 30309  
Telephone: (404) 892-5005  
Facsimile: (404) 892-5002

John D. Garretson  
Citigroup Center - 52nd Floor  
153 East 53rd Street  
New York, NY 10022-4611  
Telephone: (212) 765-5070  
Facsimile: (212) 258-2291

Attorneys for Plaintiffs SCIELE PHARMA, INC.,  
and SCIELE PHARMA CAYMAN LTD.

**CERTIFICATE OF SERVICE**

I hereby certify that on January 28, 2008, I electronically filed with the Clerk of Court **PLAINTIFFS' REPLY TO DEFENDANTS' COUNTERCLAIMS** using CM/ECF which will send electronic notification of such filing(s) to the following Delaware counsel. In addition, the filing will also be sent via hand delivery:

Richard K. Herrmann Esquire  
Mary B. Matterer, Esquire  
Morris James LLP  
500 Delaware Ave., Ste. 1500  
P.O. Box 2306  
Wilmington, DE 19899

*Attorneys for Defendants  
Mylan Pharmaceuticals, Inc. and Mylan  
Laboratories, Inc.*

I also certify that on January 28, 2008, I have sent by electronic mail and U.S. First Class Mail, the document(s) to the following non-registered participants:

William A. Rakoczy, Esquire  
Rakoczy Molino Mazzochi Siwik LLP  
6 West Hubbard Street, Suite 500  
Chicago, IL 60610

*Attorneys for Defendants  
Mylan Pharmaceuticals, Inc. and Mylan  
Laboratories, Inc.*

/s/ William J. Marsden, Jr.

William J. Marsden, Jr.